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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,061	03/01/2000	Venkat Gopalan	50093/016001	3858
21559	7590	10/04/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/516,061

Applicant(s)

GOPALAN ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004 and 21 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-11 and 13-40 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 and 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-11,13-21 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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New 37 CFR 1.121(d) states:

(d) Drawings. One or more application drawings shall be amended in the following manner: Any changes to an application drawing must be in compliance with § 1.84 and must be submitted on a replacement sheet of drawings which shall be an attachment to the amendment document and, in the header, labeled "Replacement Sheet." Any replacement sheet of drawings shall include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is amended. All changes to the drawing(s) shall be explained, in detail, in either the drawing amendment or remarks section of the amendment paper.

(1) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be included. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change to the drawings.

(2) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, must be provided when required by the examiner.

The substitute Fig. 1 submitted with the amendment of 6/28/04 is not marked as "Replacement Sheet" and will not appear in any patent issued from this application. Applicants should submit another drawing that is clearly marked at the top of the page with "Replacement Sheet". They should ascertain that the broad black lines do not obliterate the residues under them.

Claims 22-28 and 30-40 are withdrawn from further consideration as being drawn to non-elected species. The election as made in Paper No. 11. Applicants elected to prosecute SEQ ID NO:27 in Paper No. 11 and these claims attempt to add back claims to other sequences than that elected.

Claims 2, 16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 16 and 20 are confusing in that they recite sequences that were not elected for prosecution. Applicant urges that they not be limited

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to the elected species at this time because if generic claims are not allowed they will restrict the claims to the species elected. This statement is noted but the instant rejection is maintained until such time as generic claims are allowed or these claims are so limited.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 8-11, 13-21 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that "each of the 59 excluded enzymes [in claim 1] is included by reference in the specification on page 7, line 17-22" and that the Healy declaration of 10/11/02 stated that "the protein sequences for each of the RNase P protein subunits listed in claim 1, except for *Staphylococcus aureus* and *S. pneumoniae*, were available in the RNase P Database of James W. Brown on March 1, 2000...[and that] [t]he sequence of RNase P protein subunits of *Staphylococcus aureus* and *S. pneumoniae* are provided by reference in the patent applications also cited above." To start with, the examiner counts 60 excluded polypeptide sequences in claim 1, not 59 as stated by applicants.

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The excluded polypeptides are considered "essential material" since the sequence of each must be known for one of ordinary skill to know if they are infringing the instant claims. MPEP 608.01(p) states that essential material may be incorporated by reference to an issued U.S. patent, a U.S. patent application publication or a U.S. patent application that is specifically referenced and therefore will be available to the public upon the issue of this application. In this case the references are to a European application, a World Patent and a database, which are not included in the things that essential matter may reference. It is noted that although databases are not included in the categories that may be incorporated by reference, generally databases may not be used as references at all since they may be changed or deleted at any time by the owner or the person that maintains the database. Applicants have provided an expanded version of Figure 1 supposedly showing the complete sequences of all of the instant enzymes. However, this expanded Fig. 1 is not a part of the specification and in order to make it a part of the specification the inventors would have to show that these sequences are taught by references published before the filing date of this application.

Applicants further state that they "have amended claim 1 to include the rule for determining which polypeptides are genuine RNase P subunits". The supposed rule on pages 10-11 requires that the sequences "upon alignment with known RNase P sequences using the ClustalW program" have at least nine of these twenty amino acids changed as indicated in amended claim 1. There is no requirement in claim 1 that these sequences be aligned by the ClustalW program or even that these residues correspond to some referenced RNase P. Furthermore, it is not known which RNase P the sequences must be aligned or compared with. It may well make a vast difference which RNase P sequence is

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used as the reference sequence. Therefore the instant rejection is maintained.

Claims 1, 2, 8-11, 13-21 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

As noted *supra*, the amendment to claim 1 does not require the alignment to a known RNase P sequence, nor does it state that this alignment must be by the ClustalW program. The declaration of Dr. Goplan filed 6/28/04 is accepted as proof that there is only one RNase P in each species and that the *N. gonorrhoeae* and *Porphyromonas gingivalis* RNase P enzymes assayed are the same as SEQ ID NO:27 and 31.

The previous prior art rejections have been dropped in view of applicants' amendment and arguments. Both the Gopalan declaration filed 6/26/04 and the Eder declaration filed 7/21/04 have been considered.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final


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action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 30, 2004